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no. MI2002 A 001497

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Rome, 11 June 2003

The Division Director
(Name and signature)
E. Marinelli

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TO THE MINISTRY OF INDUSTRY, COMMERCE, and CRAFT TRADES. Form A

ITALIAN PATENT AND TRADEMARK OFFICE - ROME
APPLICATION for a PATENT for AN INDUSTRIAL INVENTION, RESERVE FILING, ADVANCE PUBLIC ACCESS NG:

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D TITLE class (sec/clause/sub-c) group

"INFUSION DEVICE FOR MEDICAL USE"

advance access to public: yes no x if, when: No.

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F PRIORITY: RESERVE DATE

nation or organisation	type of priority	number of application	filing date	enclosures S/R	date	no.
1)						
2)						

G CULTURE COLLECTION CENTRE, for MICROBIOLOGICAL PROCESSES - name

H SPECIAL REMARKS

RESERVE DATE

Date no.
ACCOMPANYING DOCUMENTS
no.
1) 1 prov (ob.1) total pages 27 specification incl. abstract, claims and principal drawing
2) 1 prov total tables 04 sheets of drawings (compulsory if cited in description, 1 ex.
3) 1 res letter of authorisation/power of attorney or reference
4) 0 res designation of inventor
5) 0 res foreign priority document with Italian translation
6) 0 res deed of authorisation or transfer
7) 0 res full details of applicant
8) receipt certifying payment of total: Two hundred ninety one Euros and 80 cents

compulsory
COMPILED 09.07.2002 The APPLICANT/s signature: the representative will sign as attorney
Elisa Riccardi.

CONTINUED YES/NO: no
AUTHENTIC COPY REQUIRED OF THE PRESENT ACT YES/NO : yes

MINISTRY of IND. COMM.& CRAFT TRADES, PROVINCIAL OFFICES of MILANO code 15
RECORD of FILING: APPLICATION no. MI2002A001497 reg A.
On the 9th (day) of July (month) Two Thousand and Two (year)
The applicant/s named above presented me the undersigned with the accompanying application, numbering 00 supplementary sheets, for letters patent as specified above
I. DRAFTING OFFICER'S REMARKS FILED BY office stamp
APPLICANT DRAFTING OFFICER

SUMMARY OF INVENTION WITH MAIN DRAWING FORM A

Application number	Reg. A	Filing date
Patent number		Issue date

D. TITLE

"INFUSION DEVICE FOR MEDICAL USE"

Proposed class (sez/cl/scl/) (group/subgroup)

L. ABSTRACT

A description is given of an infusion device for medical use, comprising a container (4) designed to hold a specified quantity of a liquid to be infused into a patient, a weighing device (7) associated for operation with the said container to measure the weight of the container and emit a corresponding control signal, a transport line (2) connected to the container, a pump (9) and a control unit (8) associated with the weighing device and with the said pump. The control unit is capable of detecting the end of infusion condition and of commanding the pump to stop the transport of fluid. A separator (10) for continuously separating fluid into a gaseous portion and a liquid portion operates in the said infusion line downstream of the pump and prevents the infusion of gas during the stopping transient of the pump at the end of infusion.

M. FIGURE

Fig. 1

Applicant: Gambro Lundia AB

Title: "INFUSION DEVICE FOR MEDICAL USE"

DESCRIPTION

The present invention relates to an infusion device for medical use.
In particular, the device according to the invention is used in equipment for the extracorporeal treatment of blood, for example equipment for dialysis and/or plasmapheresis, in order to provide an infusion line which can be connected to an extracorporeal blood circuit associated with the aforementioned equipment; the device in question can also be used for forming an infusion line which can be connected directly to the patient's vascular system.

As is known, a conventional infusion line comprises at least one length of tubing designed to connect a bag containing a specified infusion liquid to an extracorporeal blood circuit or directly to a patient through conventional access means such as needles, catheters or the like.

A pump, of the peristaltic type for example, can be provided on the infusion line for moving the infusion fluid in the desired way. For example, United States Patent No. 5,698,090 in the name of Hospal Industrie describes an infusion line comprising a bag containing a replacement liquid, associated for operation with a balance designed to measure the weight of the said bag and send a corresponding electrical signal to a control unit. The control unit also acts on a peristaltic pump positioned on the infusion line; in particular, the unit controls the angular velocity of the said pump in a suitable way according to the difference between the actual consumption signalled by the balance and the value set by the user. Downstream of the peristaltic pump, the infusion line is connected to a collection chamber in which the infusion liquid can be combined with the blood obtained from a venous branch of an extracorporeal blood circuit. Downstream of the aforesaid chamber, the blood, having been enriched with the infusion liquid, is returned to the patient's cardiovascular system.

The device described above can be used to control the actual flow and consequently the velocity of the infusion pump, and to achieve a separation of liquid and air such that the propagation of dangerous gas particles towards the patient is prevented.

Because of the presence of the balance and the control unit, if the total content of liquid in the bag is known, the pump can be stopped and the suction of bubbles from the bag prevented when the condition is reached in which the liquid in the bag has been used up. However, it should be noted that there is an intrinsic minimum time interval between the actual emptying of the bag and the detection of this situation by the system consisting of the balance combined with the control unit. Consequently, in order to ensure the reliable operation of the described system, it is necessary to have a collection chamber (often referred to as a "bubble trap") in the infusion line, in which a specified volume of liquid can be held constantly; in normal operating conditions, the collection chamber holds this specified volume of fluid and enables the control system and

balance to have sufficient time to detect when the end of infusion condition has actually been reached.

It should be noted that the detection of an end of infusion condition at the correct time is also important for the purpose of avoiding a discrepancy between the prescribed amount of infusion liquid for the patient and the actual infusion provided by the machine.

In addition to the solution described above, in which a balance is used to detect the end of infusion condition, widespread use has also been made in the past of solutions using level sensors, of the optical and/or ultrasonic type for example, which can interact with an infusion liquid collecting chamber, typically located in an intermediate area of the infusion line. In the presence of a specified flow of liquid from the bag, the infusion liquid collecting chamber forms a liquid level and a reservoir for separating any air bubbles.

A level sensor associated with the chamber can be used to check and detect any fall in the level, permitting immediate recognition of a danger condition caused by the end of the supply of infusion liquid.

Clearly, if they are to operate correctly, the level sensors described above for detecting any fall in level or the presence of air bubbles in the flow directed towards the patient also require the presence of a collection chamber in the infusion line, for the formation of a level which will be detectable.

In other words, according to the known technical solutions, in order to enable an end of infusion condition to be detected and to ensure the reliable separation of air from the fluid directed towards the patient, it is necessary to provide a proper collection chamber or drip chamber in the infusion line, where the infusion fluid can accumulate, thus considerably reducing its velocity.

In practice, the collection chamber has a radial dimension considerably greater than that of the infusion tube, and, in the manufacturing process, is typically made separately from the rest of the line. The various lengths of tubing forming the infusion line and the collection chamber then undergo a rather complicated assembly process which considerably increases the total costs of the infusion line. Furthermore, in the case of infusion lines interacting with level sensors, it is necessary to use optical or acoustic detectors which further increase the weight of the structure of the device. The said control system has to be programmed to coordinate and control the signals received from the sensors. Finally, all the known devices require the presence, downstream of the pump, of at least one safety valve, for example a clamp, which can close the tubing as soon as the condition of the end of infusion or the approaching end of infusion is detected. Clearly, the fluid collection chamber can separate air from the liquid only when a minimum quantity of liquid is present in the said chamber: if the liquid in the collection chamber is used up (this inevitably occurs after a certain time when the infusion liquid has been used up, unless the infusion pump is stopped at the correct time), there will be a transfer of gas towards the patient.

Finally, it should also be mentioned that there are known air-liquid separators of the type

comprising a containing body forming two adjacent chambers separated by a hydrophilic membrane; the containing body has an inlet aperture for a fluid comprising liquid and gas particles. The liquid can pass through the hydrophilic membrane and emerge through an outlet aperture. The gas which reaches the first chamber is discharged through secondary apertures positioned upstream of the hydrophilic membrane, at least one hydrophobic membrane being used at these apertures to prevent the liquid from passing through. The device which has been described allows the fluid, containing gas particles, to be separated into two parts, namely a liquid phase which emerges from the outlet aperture provided in the second chamber, and a gas phase which is released through the secondary apertures provided in the first chamber. It should be noted that the air separator device which has been described does not require a constant presence of liquid stagnating within it in order to separate the gas; in other words, the fluid passing through the separation device is continuously divided into liquid, which continues along the line, and gas, which is discharged to the exterior.

In this situation, the object of the present invention is to provide a novel infusion device for the infusion of a liquid obtained from a bag using a line having a very simple structure and overcoming all the drawbacks described above.

In particular, an object of the present invention is to provide an infusion device which does not require the use of a chamber for collecting the fluid upstream of the infusion point, and which does not require the presence of any optical or ultrasonic level sensor.

In particular, an object of the present invention is to combine efficiently, in an infusion line, the presence of a balance operating on the infusion bag with the presence of a special system capable of continuously preventing the passage of air to the patient during the detection of the end of infusion condition, in such a way as to make the whole infusion line extremely simple, efficient and reliable, so that there is theoretically no need to have further safety systems (clamps or other devices) for stopping the flow along the line.

Finally, an object of the present invention is to provide an infusion line which allows a plurality of bags to be incorporated, with a simple means of changing from one bag to the next when the liquid contained in each infusion bag is used up.

These and other objects, which will be made clearer in the following description, are essentially achieved by an infusion device according to the descriptions in one or more of the attached claims.

Brief description of the drawings

Further characteristics and advantages will be made clearer by the detailed description of a preferred, but not exclusive, embodiment of an infusion device according to the present invention.

This description is provided below with reference to the attached drawings, provided solely for guidance and therefore without restrictive intent, in which

Figure 1 is a schematic view of an infusion device according to the invention, applied to

an extracorporeal blood circuit;

Figure 2 shows a portion of the device of Figure 1, comprising a supporting element and a curved length of tubing;

Figure 3 is a view similar to that of Figure 2, in which part of the supporting element has been removed to show its internal structure more clearly;

Figure 4 is a detail view of a supporting element forming part of the device according to the invention;

Figure 5 is a section taken through the line V-V of Figure 4; and

Figure 6 shows the part of the supporting element which is removed in the view of Figure 3.

Detailed description

With reference to the attached figures, a description will be given of an infusion device 3 according to the invention. The device 3 has an infusion line 2 and at least one container 4 designed to hold a specified quantity of a liquid to be infused into a patient; in particular, the infusion point 5 can be positioned in a specified area of an extracorporeal blood circuit, or, alternatively, can be connected directly to the patient. The device 3 can also comprise a plurality of containers 4, which can be sequentially brought into fluid communication with the infusion point by opening and closing corresponding shut-off elements 6, such as clamps or the like, which may be manually or automatically operated. A weighing device 7, such as a balance, is associated for operation with the infusion liquid container or containers, to detect the total weight of the container or containers and send a corresponding control signal. In practice, the control signal is a signal related to the total weight measured by the balance 7 during the treatment. This signal is transmitted to a control unit 8 associated with the weighing device; the unit can sample and store the weight measured by the balance at finite time intervals, for example at regular intervals. Thus the control unit can determine the actual flow passing through the line and suitably adjust movement means 9 associated with the said line whenever a discrepancy is found between the actual flow and the desired flow. It should be noted that the movement means can comprise at least one pump, for example a peristaltic pump, or, in the case of gravity operation for example, a flow control valve, for example an electromagnetic clamp. Typically, the desired flow can be set by the user or pre-programmed in the control unit and, in any case, can be a value which is constant or variable over time. The control unit can determine the decrease in the actual weight of the infusion liquid container, and can adjust the movement means, if necessary, to obtain the said desired flow along the line. When the total weight of the content of each container is known, the control unit 8 can also detect at least a condition of emptying or end of infusion, and activate a corresponding control procedure. This procedure can comprise a stage of commanding the movement means 9 to stop the transport of fluid along the said line and/or a stage of signalling that the container is empty or that a specified volume of liquid has been used up. If the device comprises two or more liquid containers 4, the line 2 will also have a plurality of

branches 2a, each designed to bring a corresponding container into fluid communication with a common part 2b of the line 2 and thus with the infusion point 5. In this case, each branch has a flow shut-off element 6 which can be switched between an open and a closed position, to selectively permit or prevent the passage of fluid. The flow shut-off elements can be activated manually or commanded sequentially by the control unit 8. For example, the control unit can be programmed so that, when an empty condition of a container is detected, it can command the closing of the shut-off element 6 located in the branch 2a related to the empty container 4, and the opening of one of the shut-off elements 6 located in a branch 2a corresponding to a container in which liquid is present. This procedure can be repeated until all the containers have been emptied.

The device in question comprises a continuous fluid separator 10, located in the infusion line, for separating the fluid supplied from the container or containers 4 into a gas portion and a liquid portion; this separator can allow only the liquid to continue along the infusion line, while separating and discharging towards the exterior any gas bubbles supplied from the container 4. In particular, when the infusion liquid in a container has been used up, the separator receives any gas and discharges it to the exterior, thus preventing the passage of gaseous substances downstream of the section in which this separator operates. The continuous separator 10 comprises a containing body 11 having at least one inlet 12 for receiving a fluid supplied from the container, at least a first outlet 13 for receiving a liquid portion of the said flow and sending it downstream of the selector to the infusion point, at least a second outlet 14 for receiving the said gaseous portion of the said fluid and discharging it towards the exterior, and selector means 15 interposed between the said inlet and the said first outlet and capable of continuously separating the said fluid into a gaseous portion and the said liquid portion. The selector means 15 comprise at least one hydrophilic membrane 16 having one side 16a facing the first outlet and one side 16b facing the said inlet for receiving the said fluid and transferring only liquid towards the first outlet; the selector means 15 also comprise at least one hydrophobic membrane 17 having one side 17a facing the said second outlet 14 and one side 17b facing the said inlet aperture 12 to receive the said fluid and transfer only gas towards the second outlet.

With reference to the extension of the infusion line, the separator 10 is interposed between the said movement means 9 and the infusion point 5, and, in particular, is positioned immediately downstream of the said movement means. As can be seen in the attached figures, the device 3 comprises a rigid supporting element 1, holding opposing portions of a first length of tubing 18 of the line 2 and specifically designed to interact with the movement means 9. In practice, the rigid support holds the first length of tubing 18 in such a way that this first length has a curved shape and a specified axial extension. The supporting element is positioned transversely with respect to the mid-line axis of the opposing portions of the first length of tubing, and enables the line to be manipulated easily to allow the first length to be easily fitted around a rotor of a peristaltic pump. Upstream of this first length of tubing, the line comprises a second

length of tubing 19 extending between the said container and the rigid support and placed in fluid communication with the first length. As mentioned, the second length of tubing 19 can consist of a single duct connected to a single liquid container 4, or can branch terminally into a plurality of branches 2a, each connected to a corresponding container.

A description will now be given of the detailed structure of the rigid supporting element 1, which comprises a first lateral portion 20, forming the said containing body 11, and a second lateral portion 22, of tubular profile, to which are fixed corresponding ends of the said first and the said second lengths 18 and 19 of the line 2; the second lateral portion and the first lateral portion are connected rigidly together by a rigid cross-piece 23 provided with at least one through hole 24 which can act as an element for attaching the rigid support to a support wall which is not illustrated; the rigid cross-piece is essentially flat and parallel to a plane in which the first length of tubing lies.

The containing body 11 formed by the first portion comprises a base 25 and a cover portion 26, which interact with each other to form a passage 27 for fluid between the said inlet 12, on the one hand, and the said first and second outlets 13, 14, on the other hand. More precisely, the base 25 forms a through channel 28 for putting the said passage 27 in fluid communication with the exterior. This through channel extends orthogonally to the plane in which the supporting element 1 lies, and is located in the proximity of a peripheral area of the base; thus, when the device is mounted on the peristaltic pump in operating conditions, the channel is located in a topmost area of the base. As will be seen in Figure 5, the passage 27 within the containing body is essentially divided by the hydrophilic membrane 16 into two half-parts or chambers 27a and 27b. Because of its special positioning, the channel 28 is located in the uppermost point of the chamber 27a (located upstream with respect to the direction of flow) into which the passage is divided, in order to discharge any gas efficiently. For this purpose, the hydrophobic membrane 17 operates in an inlet section of the channel facing the interior of the containing body. With reference to Figure 5 again, it will be noted that the base 25 comprises an incorporated first tubular connecting element 29 for receiving one end of the first length of tubing. In turn, the cover portion 26 comprises an incorporated second tubular connecting element 30 having an axis of extension inclined with respect to that of the said first tubular element. The second connecting element, for example a Luer connector, can be connected directly to a T-shaped connector of an extracorporeal blood circuit 33, upstream or downstream of a blood treatment unit 34 (a dialysis filter or other device). Thus, since a direct connection to the extracorporeal blood circuit is possible, it becomes unnecessary to have a tube downstream of the separator; this provides the advantage of preventing any possible involuntary blockage which would be difficult to detect by means of the sensor system associated with the extracorporeal circuit. It should be noted in this context that any infusion liquid transport tube located downstream of the separator would, if the separator were blocked, cause a pressure stress for a certain period of time, affecting the separator and the membranes in particular, as well as the liquid seals. It should also be noted that the rigid support is thin, so that the whole line can be installed to occupy very small volumes. Nevertheless, the efficiency of the system is not reduced, because of the particular structure of the containing body and the positions of the membranes; in

particular, the hydrophilic membrane 16 is interposed between the base and the cover portion, and extends essentially through the whole containing body 11; the base 25 and the cover portion 26 comprise corresponding base walls 25a and 26a and corresponding perimetric edges 25b and 26b emerging from the base walls to form the passage through which the fluid is transported. The hydrophilic membrane extends parallel to the base walls in a position separated from the walls, thus providing an active surface essentially equal to the area of the containing body seen in plan view. It should also be noted that the containing body has a plurality of projections 31, 32 emerging from the base wall of the said base and from the base wall of the said cover portion. In detail, the projections 31 associated with the base comprise teeth distributed uniformly over the surface of the base wall of the said base, while the projections 32 associated with the cover portion comprise angularly spaced deflectors for guiding the liquid flow towards the first outlet. In terms of construction, the base of the containing body, the rigid cross-piece and the second lateral portion are made in a single piece, while the cover portion is fixed to the base after the hydrophobic and hydrophilic membranes have been placed in position.

CLAIMS

1. Infusion device for medical use, comprising:

- at least one container (4) designed to hold a specified quantity of a liquid to be infused into a patient;
- a weighing device (7) associated for operation with the said container to measure the weight of the container and emit a corresponding control signal;
- a transport line (2) connected to the said container to convey the said liquid, in operating conditions, towards an infusion point;
- means (9) for moving a quantity of the said liquid along the said line;
- a control unit (8) associated with the weighing device and with the said movement means, the said control unit receiving the said control signal and being capable of detecting at least one end of infusion condition, the said device being characterized in that it has a continuous fluid separator (10) capable of separating the fluid into a gaseous portion and a liquid portion, the said separator operating in the said infusion line.

2. Device according to Claim 1, characterized in that the said separator comprises a containing body (11) having

i. at least one inlet (12) for receiving a fluid obtained from the said container;

ii. at least a first outlet (13) for receiving a liquid portion of the said fluid;

iii. selector means (15) interposed between the said inlet and the said first outlet and capable of continuously separating the said fluid into a gaseous portion and a liquid portion.

3. Device according to Claim 2, characterized in that the containing body of the separator comprises at least a second outlet (14) for receiving the said gaseous portion of the said fluid.

4. Device according to Claim 2, characterized in that the selector means comprise at least one hydrophilic membrane (16) having one side facing the first outlet and one side facing the said inlet, for receiving the said fluid and transferring only liquid towards the first outlet.

5. Device according to Claim 3 and according to Claim 4, characterized in that the selector means comprise at least one hydrophobic membrane (17) having one side facing the said second outlet and one side facing the said inlet aperture, for receiving the said fluid and transferring only gas towards the second outlet.

6. Device according to Claim 1, characterized in that the separator (10) is interposed between the said movement means (9) and the said infusion point.

7. Device according to Claim 1, characterized in that the separator device (10) is positioned immediately downstream of the said movement means (9).

8. Device according to Claim 2, characterized in that it comprises a rigid support (1) holding opposite ends of a first length of tubing (18) of the line (2) designed to interact with the movement means (9), the first length of tubing having a curved shape and a specified axial extension.

9. Device according to Claim 8, characterized in that the said line (2) comprises a second length of tubing (19) extending between the said container (4) and the said rigid supporting element (1) and put into fluid communication with the first length.

10. Device according to Claim 8, characterized in that the said rigid supporting element (1) comprises a first lateral portion (20) forming the said containing body (11).

11. Device according to Claim 10, characterized in that the said rigid support comprises a second lateral portion (22) with a tubular profile to which are fixed corresponding ends of the said first and said second portions of the line (18, 19), this second lateral portion being spaced apart from the first portion.

12. Device according to Claim 10, characterized in that the said containing body (11) comprises a base (25) and a cover portion (26), interacting with each other to form a passage (27) for fluid between the said inlet (12) and the said first and second outlets (13, 14).

13. Device according to Claim 12, characterized in that the said base (25) forms a through channel (28) for putting the said passage (27) into fluid communication with the exterior, the said hydrophobic membrane (17) operating in the said channel.

14. Device according to Claim 12, characterized in that the said base (25) comprises an incorporated first tubular connecting element (29).

15. Device according to Claim 12, characterized in that the said cover portion (26) comprises an incorporated second tubular connecting element (30) having an axis of extension inclined with respect to that of the said first tubular element.

16. Device according to Claim 12, characterized in that the said hydrophilic membrane (16) is interposed between the said base (25) and the said cover portion (26), and extends essentially throughout the said containing body (11).

17. Device according to Claim 12, characterized in that each of the said base and the said cover portion comprises a corresponding base wall and a corresponding perimetric edge emerging from the said base wall, the said membrane extending parallel to the said base walls in a position separated from them.

18. Device according to Claim 17, characterized in that the containing body has a plurality of projections (31) emerging from the base wall of the said base.

19. Device according to Claim 17, characterized in that the containing body has a plurality of projections (32) emerging from the base wall of the said cover portion.

20. Device according to Claim 18, characterized in that the projections comprise teeth distributed uniformly over the surface of the base wall of the said base.

21. Device according to Claim 19, characterized in that the projections comprise deflectors spaced angularly to guide the flow of liquid towards the first outlet.

22. Device according to Claims 10 and 11, characterized in that the first and second lateral portion (20, 22) are rigidly connected by a rigid cross-piece (23).

23. Device according to Claim 22, characterized in that the base of the containing body, the

rigid cross-piece and the second lateral portion are made in a single piece.

24. Device according to Claim 22, characterized in that the rigid cross-piece is essentially flat and parallel to a plane in which the said first length of tubing lies.

25. Device according to Claim 1, characterized in that the said control unit (8) is capable of executing an appropriate end of infusion procedure when the end of infusion condition is detected.

26. Device according to Claim 1, characterized in that the said end of infusion procedure comprises the stage of commanding the movement means (9) to stop the transport of fluid along the said line.

27. Device according to Claim 1, characterized in that the said end of infusion procedure comprises the stage of signalling that an end of infusion condition has been reached.

28. Device according to Claim 1, characterized in that it comprises a plurality of said containers (4), the said infusion line having a plurality of branches for the fluid connection of each container to the said infusion point, and a corresponding flow shut-off element (6) acting on each of the said branches.

29. Device according to Claim 28, characterized in that the said end of infusion procedure comprises the stage of commanding the opening of a shut-off element (6) associated with a container which is not empty.

30. Equipment for extracorporeal blood treatment, comprising a device according to any one of the preceding claims.

31. Equipment according to Claim 30, characterized in that it comprises an extracorporeal circuit (33) and a blood treatment unit (34) positioned in the said circuit (33), the said second connecting element being directly and removably connected to a connector of the extracorporeal blood circuit (33) upstream or downstream of a blood treatment unit (34).